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IRRITATION POTENTIAL OF COMPONENTS OF THE M-258A-1 DECONTAMINAT--ETC(U)
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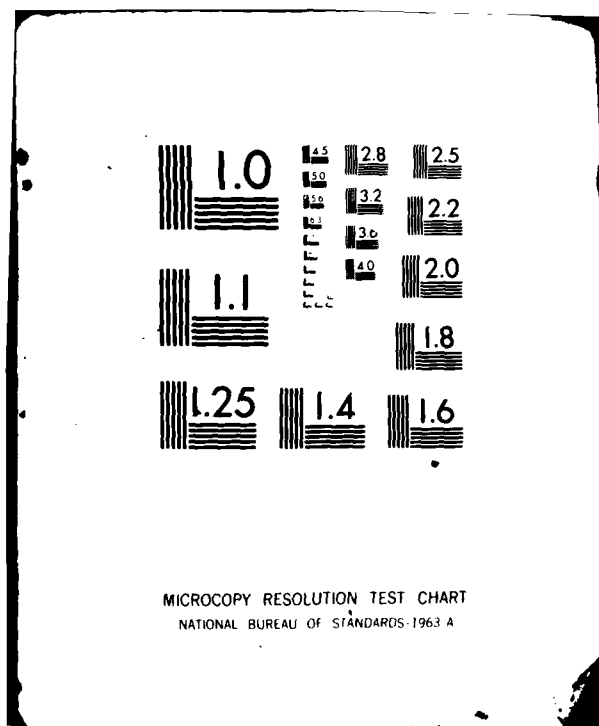
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20. ABSTRACT (Continue on reverse side if necessary and identify by block number)		
<p>The impact of rinsing on the primary dermal irritation caused by the components of the Prototype M-258A-1 Decontamination Kit was assessed by using a modified Draize test. The test called for applying the components as they are intended to be applied under field conditions. Approximately 0.03 to 0.1 g of test substance was applied per dose site. Immediately the sites were rinsed three times with saline. The rinsing reduced the primary dermal irritation caused by the solutions.</p>		

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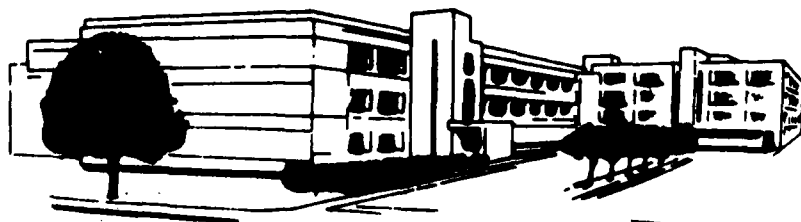
**PRIMARY DERMAL IRRITATION POTENTIAL OF COMPONENTS
OF THE M-258A-1 DECONTAMINATION KIT (Study 8)**

WARREN W. JEDERBERG, MS, CPT MS
and
JOHN T. FRUIN, DVM, PhD, LTC VC

**DIVISION OF CUTANEOUS HAZARDS
and
TOXICOLOGY GROUP,
DIVISION OF RESEARCH SUPPORT**

NOVEMBER 1981

Toxicology Series 21



LETTERMAN ARMY INSTITUTE OF RESEARCH PRESIDIO OF SAN FRANCISCO CALIFORNIA 94129

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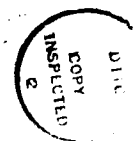
In conducting the research described in this report, the investigation adhered to the "Guide for the Care and Use of Laboratory Animals," as promulgated by the Committee on Revision of the Guide for Laboratory Animal Facilities and Care, Institute of Laboratory Animal Resources, National Research Council.

This material has been reviewed by Letterman Army Institute of Research and there is no objection to its presentation and/or publication. The opinions or assertions contained herein are the private views of the author(s) and are not to be construed as official or as reflecting the views of the Department of the Army or the Department of Defense. (AR 360-5)

John D. Marshall 20 Nov 81
(Signature and date)

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PREFACE

Primary Dermal Irritation GLP Study Report

TESTING FACILITY: Letterman Army Institute of Research
Presidio of San Francisco, CA 94129

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Presidio of San Francisco, CA 94129

PROJECT: Medical Defense Against Chemical Agents 3S162772.875

GLP STUDY NUMBER: 81026

STUDY DIRECTOR: LTC (P) John T. Fruin, DVM, PhD, VC, Diplomate of
American College of Veterinary Preventive Medicine

PRINCIPAL INVESTIGATOR: CPT Warren W. Jederberg, MS, MS

RAW DATA: A copy of the final report, study protocol, raw data, and
standard operating procedures will be retained in the LAIR
Archives.

TEST SUBSTANCES: A. Decon I, consisting of a pad pre-wetted with
hydroxyethane (ethanol) 72 \pm 2% phenol 10 \pm 0.5%,
sodium hydroxide 5 \pm 0.5%, ammonium hydroxide
0.2 \pm 0.05% and water was used to wipe the back of
rabbits for 1 minute.

B. Decon II, consisting of a pad impregnated with a
quantity of crystalline chloramine B and an equal
quantity of liquid contained in breakable glass
ampoules covered with nylon mesh. The liquid con-
tains hydroxyethane (ethanol) 45 \pm 2%, zinc
chloride 5 \pm 0.5% and water. Just prior to dosing,
the ampoules were broken and thus the chloramine B
impregnated pad was saturated with liquid. Decon II
was used to wipe the backs of rabbits for 2-3 min.

C. Decon I and Decon II were used to wipe the same
area of the back for 1 and 2-3 minutes,
respectively.

D. Control (no treatment)

WORK UNIT: 302 Studies on Potential Dermal Irritation of M-258A-1 Kit


PURPOSE: The purpose of this study was to determine the effects of
removing the chemicals used in the M-258A-1 Kits on abraded
and intact skin of rabbits with saline damped pads (occluded and
non-occluded).

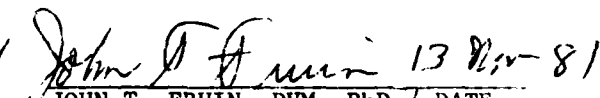
ACKNOWLEDGMENTS

The authors wish to thank SSG Lance White; SP4 Thomas Kellner, BS; PFC Evelyn Zimmerman; Carolyn Lewis, MS; for assistance in performing the research, and for advice in scoring the irritation reactions. The authors also wish to thank M. Mershon, VMD; LTC (P) E. Houston, PhD, MS; LTC R. Howarth, VMD, VC, of the U.S. Army Medical Research Institute of Chemical Defense, Aberdeen Proving Grounds, MD, for providing prototype M-258A-1 Decontamination Kits and background information.

Signatures of Principal Scientists Involved
In The Study

We, the undersigned, believe the study, GLP Study number 81026, described in this report to be scientifically sound and the results and interpretation to be valid. The study was conducted to comply, to the best of our ability, with the Good Laboratory Practice Regulations for Nonclinical Laboratory Studies outlined by the Food and Drug Administration.


WARREN W. FEDERBERG, MS / DATE
CPT, MS
Principal Investigator

 13 Nov-81
JOHN T. FRUIN, DVM, PhD / DATE
LTC (P), VC
Study Director



DEPARTMENT OF THE ARMY
LETTERMAN ARMY INSTITUTE OF RESEARCH
PRESIDIO OF SAN FRANCISCO, CALIFORNIA 94129

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ATTENTION OF:

SGRD-ULZ-QA

18 November 1981

MEMORANDUM FOR RECORD

SUBJECT: Report of GLP Compliance

I hereby certify that in relation to LAIR GLP study 81026 the following inspections were made:

1 Sep 81, 0830 Hrs
1 Sep 81, 0900 Hrs
2 Sep 81
4 Sep 81

Inspection findings were reported to the Study Director on 31 Aug 81. These inspections are also included in the Oct 81 report to management and the Study Director.

JOHN C. JOHNSON
CPT, MS
Quality Assurance Officer

PRIMARY DERMAL IRRITATION POTENTIAL OF COMPONENTS OF THE M-258A-1
DECONTAMINATION KIT (Study 8)

An evaluation of the Prototype M-258A-1 Decontamination Kit for primary dermal irritation potential by using the modified Draize test (1) was recently completed (2). That evaluation using the standard method to apply the test compound produced evidence of severe irritation potential. Further testing was determined to be necessary to determine the kit's irritation potential under conditions of proposed field usage.

Deviation from standards

Rather than applying liquid test substance on gauze, liquid impregnated pads from the M-258A-1 Decontamination Kit were cut into approximately one inch squares. Decon I squares were used to wipe the test area on the backs of rabbits for 1 minute. Decon II squares were used similarly, except the wiping was for 2 minutes. For Decon I plus Decon II the test site was first wiped for 1 minute with Decon I and then for 2 minutes with Decon II.

Immediately after applying the test compounds, the sites were washed with saline. This was done by scrubbing the application site five times with each of three surgical pads soaked in saline.

The test sites on one group of animals were occluded as per SOP-OP-STX-34. The other group was not occluded.

Chemical analyses were not conducted in an effort to conserve resources except for measuring the pH. Our intent was to evaluate the product; the data and reports were not intended for presentation to FDA. The pH of Decon I was 11.7, and Decon II was 6.8. Chemical composition was considered to be that printed on the outer container for the Prototype M-258A-1 Decontamination Kit (Table 1 and 2). The compound was assumed to be stable under conditions of storage and use. Compound purity was unknown.

TABLE 1 (3)

CHEMICAL ANALYSIS OF DECON I
(pH = 10.7 - 10.8)

Component	ETOH	H ₂ O	Phenol	NaOH	NH ₄ OH
%	72 \pm 2%	q.s.	10 \pm 0.5%	5.0 \pm 0.5%	0.2 \pm 0.05%
Name	ethanol	water	phenol	sodium hydroxide	ammonium hydroxide
Molecular Structure	C ₂ H ₆ O	H ₂ O	C ₆ H ₆ O	NaOH	NH ₄ OH
Molecular Weight	46.07	18.016	94.12	40.01	35.036

TABLE 2 (3)

CHEMICAL ANALYSIS OF DECON II
(pH = 6.5 - 6.6)

Component	*LIQUID PORTION			*SOLID PORTION
	ETOH	H ₂ O	ZnCl ₂	Chloramine B
%	45 \pm 2%	50 \pm 2.5%	5 \pm 0.5%	100%
Name	ethanol	water	zinc chloride	Chloramine B (N-Chlorobenzene-sulfamido-sodium)
Molecular Structure	C ₂ H ₆ O	H ₂ O	ZnCl ₂	C ₆ H ₅ Cl NNaO ₂ S
Molecular Weight	46.07	18.016	136.29	213.64

* Equal quantities of liquid and solid are mixed to form Decon II.

Objective of Study

The objective of this study was to determine the primary dermal irritation, produced by the chemicals in the M-258A-1 Prototype Decontamination Kit, is reduced by immediate rinsing of the abraded and intact skin of rabbits. The study was designed to stimulate field conditions for using the M-258A-1 Decontamination Kit.

METHODS

Historical Listing of Study Events

28 Aug 81	Animals were weighed and sites for exposure were randomized.
28 Aug 81	Animals were close clipped and areas marked.
1 Sep 81	animals were weighed and dosed.
1-15 Sep 81	Animals were observed daily, only significant or abnormal observations were recorded.
2 Sep 81	Bandages removed. 24-hr post exposure score.
4 Sep 81	72-hr post exposure score.
8 Sep 81	7-day post exposure score, weight taken.
15 Sep 81	Animals were scored, (14 day after exposure) and weights taken. Animals were removed from study.

Animal Data

Animal: New Zealand White Rabbits

Sex: Female

Source: Elkhorn Rabbitry

Pre-test conditioning:

- a. Some of the animals used were those that had been used previously in other tests and were free from all indications of dermal lesions. All animals had been rested for at least three weeks. The previous test compounds were candidate insect repellents and we do not believe there was any carry over effect.

Dosing Procedures

Method and frequency of administration were dictated by SOP-OP-STX-34. The backs of the animals were close clipped and divided into quadrants designated I,II,III, and IV (SOP-OP-STX-34). Areas I and IV were intact on all animals, and areas II and III were abraded by making two perpendicular scratches in the stratum corneum of the skin about 1 1/2 inch long by using an escarifier. The four application sites were about 10 cm apart. A standard latin square table was used to randomize the test sites (SOP-OP-STX-34). The test substance impregnated pads were wiped over the test sites for 1, 2 and 3 minutes (see deviation to standards). An Elizabethan collar was placed around each animal's neck to keep animals from self-mutilating the treatment site.

RESULTS

Scoring (SOP-OP-STX-34)

Six animals in each group were exposed to the chemicals. Animals were scored at 24 and 72 hours, 7 and 14 days for edema/erythema (Table 3). Tabular data appear in Appendix A and B. The data in Appendix A were recorded for rabbits on which exposure sites were occluded for 24 hours. No occlusion was made on the rabbits represented by the data in Appendix B. Abraded areas (sites II and III) and intact areas (sites I and IV) were graded separately as well as together. The scores obtained were used as a basis for categorization. Primary irritation potential values were calculated from 24 and 72 hour scores.

TABLE 3
EVALUATION OF SKIN REACTIONS (4)

Erythema and Eschar Formation

No erythema	0
Very slight erythema (barely perceptible)	1
Well defined erythema	2
Moderate-to-severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injurious in depth)	4
Possible total erythema score	4*

Edema Formation

No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well defined by definite raising)	2
Moderate edema (edges raised approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond area of exposure)	4
Possible total edema score	4*

Possible total score for primary irritation	8
---	---

* Any skin reaction more serious than severe erythema, severe edema, vesiculation, ulceration, or necrosis places the chemical in Category IV.

Compounds producing combined averages (intact and abraded scores of 0.51 - 2 are considered mildly irritating (Category II), if the intact score is greater than 0.5, whereas those with indexes from 2 to 5 are moderate irritants (Category III). Category IV irritants are compounds producing moderate to severe primary irritation of intact skin surrounding an abrasion. In addition, these compounds produce necrosis, vesticulation, ulceration, eschars and a combination of these features. (Category assignment and interpretation, A.H. McCreesh, personal communication, 1980.) Tables 4 and 5 demonstrate the primary irritation indexes for the exposed areas.

TABLE 4

PRIMARY DERMAL IRRITATION INDEX FOR M-258A-1 DECONTAMINATION KIT
AFTER RINSING THREE TIMES AND OCCLUDING FOR 24 HOURS

Chemical	Intact Score	Abraded Score	Combined Score	Category
Decon I	0.17	0.50	0.33	I
Decon II	0.00	0.67	0.33	I
Decon I+II	0.00	0.50	0.25	I
Control	0.00	0.00	0.00	I

TABLE 5

PRIMARY DERMAL IRRITATION INDEX FOR M-258A-1 DECONTAMINATION KIT
AFTER RINSING THREE TIMES AND NOT OCCLUDING

Chemical	Intact Score	Abraded Score	Combined Score	Category
Decon I	0.00	1.50	0.75	I
Decon II	0.00	0.50	0.25	I
Decon I+II	0.00	1.00	0.50	I
Control	0.00	0.17	0.08	I

DISCUSSION

In all instances the rinsing seemed adequate to prevent significant irritation.

CONCLUSIONS

Simple rinsing will reduce the primary dermal irritation caused by the components of the M-258A-1 Prototype Decontamination Kit.

RECOMMENDATION

Recommendations will be made after the current series of studies is completed.

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1. DRAIZE, J., H.Z. WOODARD, and H.O. CALVERY. Method for the study of irritation and toxicity of substances applied topically to the skin and mucous membranes. J Pharmacol Exp Ther. 83:377-390, 1944
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Summary of Primary Skin Irritation Test Data (Occluded)

	Page
APPENDIX A-1 Decon I	14
APPENDIX A-2 Decon II	15
APPENDIX A-3 Decon I and II	16
APPENDIX A-4 Control	17

APPENDIX A

APPENDIX A-1

Summary of Primary Skin Irritation Test Data

GLP Study No. 81026 Chemical Name Decon I Conc N/A Solvent N/A Amt Applied 0.03-0.1 g Code A
 Date of Application 1 Sept 81
 Principal Investigator CPT Jederberg

Irritation Scores

		Intact Skin Sites				Abraded Skin Sites				
Rabbit No.	Site	Erythema		Edema		Site	Erythema		Edema	
		24 hr	72 hr	24 hr	72 hr		24 hr	72 hr	24 hr	72 hr
F8100042	I	1	0	0	0					
F8100043						II	1	0	0	0
F8100051	IV	0	0	0	0					
F8100081						III	1	1	0	0
F8100089	I	0	0	0	0					
F8100094						III	0	0	0	0
Total:		a 1	b 0	a 0	b 0		a 2	b 1	a 0	b 0
		a+b 1		a+b 0			a+b 3		a+b 0	

CI +
1

CA +
3

Intact Score = $\frac{CI}{2 \times \text{No. of Sites on test}}$ $\frac{1}{2 \times 3} = 0.17$

Abraded Score = $\frac{CA}{2 \times \text{No. of Sites on test}}$ $\frac{3}{2 \times 3} = 0.50$

Total Score = $\frac{CI+CA}{2 \times \text{No. of Sites on test}}$ $\frac{4}{2 \times 6} = 0.33$

Primary Skin Irritation Index Category I

Remarks: Occluded

APPENDIX A-2

Summary of Primary Skin Irritation Test Data

GLP Study No. 81026 Chemical Name Decon II Conc N/A Solvent N/A Amt Applied 0.03-0.1 g Code B
 Date of Application 1 Sep 81
 Principal Investigator CPT Jederberg

Irritation Scores

		Intact Skin Sites				Abraded Skin Sites				
Rabbit No.	Site	Erythema		Edema		Site	Erythema		Edema	
		24 hr	72 hr	24 hr	72 hr		24 hr	72 hr	24 hr	72 hr
F8100042						II	1	0	0	0
F8100043	I	0	0	0	0					
F8100051						III	1	0	0	0
F8100081	IV	0	0	0	0					
F8100089						II	1	1	0	0
F8100094	I	0	0	0	0					
Total:		a	b	a	b		a	b	a	b
		0	0	0	0		3	1	0	0
		a+b		a+b			a+b		a+b	
		0		0			4		0	
		CI +					CA +			
		0					4			

$$\text{Intact Score} = \frac{C^I}{2 \times \text{No. of Sites on test}} = \frac{0}{(2 \times 3)} = 0.00$$

$$\text{Abraded Score} = \frac{C^A}{2 \times \text{No. of Sites on test}} = \frac{4}{(2 \times 3)} = 0.67$$

$$\text{Total Score} = \frac{C^I + C^A}{2 \times \text{No. of Sites on test}} = \frac{4}{(2 \times 6)} = 0.33$$

Primary Skin Irritation Index Category I

Remarks: Occluded

APPENDIX A-3

Summary of Primary Skin Irritation Test Data

GLP Study No. 81026 Chemical Name Decon I + II Conc N/A Solvent N/A Amt Applied 0.03-0.1 g each I + II Code C
 Date of Application 1 Sep 81
 Principal Investigator CPT Jederberg

Irritation Scores

		Intact Skin Sites				Abraded Skin Sites				
Rabbit No.	Site	Erythema		Edema		Site	Erythema		Edema	
		24 hr	72 hr	24 hr	72 hr		24 hr	72 hr	24 hr	72 hr
F8100042						III	1	0	0	0
F8100043	IV	0	0	0	0					
F8100051	I	0	0	0	0					
F8100081						II	1	1	0	0
F8100089						III	0	0	0	0
F8100094	IV	0	0	0	0					
Total:		a 0	b 0	a 0	b 0		a 2	b 1	a 0	b 0
		a+b	0	a+b	0		a+b	3	a+b	0
		$\frac{CI}{0}$				$\frac{CA}{3}$				

Intact Score = $\frac{CI}{2 \times \text{No. of Sites on test}}$ $\frac{0}{(2 \times 3)} = 0.00$

Abraded Score = $\frac{CA}{2 \times \text{No. of Sites on test}}$ $\frac{3}{(2 \times 3)} = 0.50$

Total Score = $\frac{CI + CA}{2 \times \text{No. of Sites on test}}$ $\frac{3}{(2 \times 6)} = 0.25$

Primary Skin Irritation Index Category I

Remarks: Occluded

APPENDIX A-4

Summary of Primary Skin Irritation Test Data

GLP Study No. 81026 Chemical Name Control Conc N/A Solvent N/A Amt Applied None Code D
 Date of Application 1 Sep 81
 Principal Investigator CPT Jederberg

Irritation Scores

		Intact Skin Sites				Abraded Skin Sites				
Rabbit No.	Site	Erythema		Edema		Site	Erythema		Edema	
		24 hr	72 hr	24 hr	72 hr		24 hr	72 hr	24 hr	72 hr
F8100042	IV	0	0	0	0					
F8100043						III	0	0	0	0
F8100051						II	0	0	0	0
F8100081	I	0	0	0	0					
F9100089	IV	0	0	0	0					
F8100094						II	0	0	0	0
Total:		a 0	b 0	a 0	b 0		a 0	b 0	a 0	b 0
		a+b		a+b			a+b		a+b	
		0		0			0		0	

$$\frac{CI}{0}$$

$$\frac{CA}{0}$$

$$\text{Intact Score} = \frac{CI}{2 \times \text{No. of Sites on test}} = \frac{0}{(2 \times 3)} = 0.00$$

$$\text{Abraded Score} = \frac{CA}{2 \times \text{No. of Sites on test}} = \frac{0}{(2 \times 3)} = 0.00$$

$$\text{Total Score} = \frac{CI + CA}{2 \times \text{No. of Sites on test}} = \frac{0}{(2 \times 6)} = 0.00$$

Primary Skin Irritation Index Category I

Remarks: Occluded

Summary of Primary Skin Irritation Test Data (Non-occluded)

	Page
APPENDIX B-1 Decon I	18
APPENDIX B-2 Decon II	19
APPENDIX B-3 Decon I and II	20
APPENDIX B-4 Control	21
	APPENDIX B

APPENDIX B-1

Summary of Primary Skin Irritation Test Data

GLP Study No. 81026 Chemical Name / Conc. / Solvent / Amt Applied / Code
 Date of Application 1 Sep 81 Decon 1 N/A N/A 0.03-0.1 g A
 Principal Investigator CPT Jederberg

Irritation Scores

		Intact Skin Sites				Abraded Skin Sites				
Rabbit No.	Site	Erythema		Edema		Site	Erythema		Edema	
		24 hr	72 hr	24 hr	72 hr		24 hr	72 hr	24 hr	72 hr
F8100048						II	1	1	1	1
F8100050	IV	0	0	0	0					
F8100052	I	0	0	0	0					
F8100078						II	1	1	0	0
F8100083						III	1	1	1	0
F8100093	IV	0	0	0	0					
Total:		a	b	a	b		a	b	a	b
		0	0	0	0		3	3	2	1
		a+b		a+b			a+b		a+b	
		0		0			6		3	
		C ^I +		C ^A +						
		0		9						

Intact Score = $C^I / 2 \times \text{No. of Sites on test}$ $0 / (2 \times 3) = 0.00$

Abraded Score = $\frac{C^A}{C^I + C^A} / 2 \times \text{No. of Sites on test}$ $9 / (2 \times 3) = 1.50$

Total Score = $2 \times \frac{C^I + C^A}{\text{No. of Sites on test}}$ $9 / (2 \times 6) = 0.75$

Primary Skin Irritation Index Category I

Remarks: Non-Occluded

APPENDIX B-2
Summary of Primary Skin Irritation Test Data

GLP Study No. 81026 Chemical Name Decon II Conc N/A Solvent N/A Amt Applied 0.03-0.1 g Code B
Date of Application 1 Sep 81
Principal Investigator CPT Jederberg

Irritation Scores

		Intact Skin Sites				Abraded Skin Sites				
Rabbit No.	Site	Erythema		Edema		Site	Erythema		Edema	
		24 hr	72 hr	24 hr	72 hr		24 hr	72 hr	24 hr	72 hr
F8100048	IV	0	0	0	0					
F8100050						III	0	0	0	0
F8100052						II	1	1	1	0
F8100078	I	0	0	0	0					
F8100083	IV	0	0	0	0					
F8100093						III	0	0	0	0
Total:		a	b	a	b		a	b	a	b
		0	0	0	0		1	1	1	0
		a+b		a+b			a+b		a+b	
		0		0			2		1	
		CI +				CA +				
		0				3				

Intact Score = $\frac{CI}{2 \times \text{No. of Sites on test}}$ $\frac{0}{(2 \times 3)} = 0.00$

Abraded Score = $\frac{CA}{2 \times \text{No. of Sites on test}}$ $\frac{3}{(2 \times 3)} = 0.50$

Total Score = $\frac{CI+CA}{2 \times \text{No. of Sites on test}}$ $\frac{3}{(2 \times 6)} = 0.25$

Primary Skin Irritation Index Category I

Remarks: Non-Occluded

APPENDIX B-3

Summary of Primary Skin Irritation Test Data

GLP Study No. 81026 Chemical Name Decon I + II Conc N/A Solvent N/A Amt Applied 0.03-0.1 g each I + II Code C
 Date of Application 1 Sep 81
 Principal Investigator CPT Jederberg

Irritation Scores

		Intact Skin Sites				Abraded Skin Sites				
Rabbit No.	Site	Erythema		Edema		Site	Erythema		Edema	
		24 hr	72 hr	24 hr	72 hr		24 hr	72 hr	24 hr	72 hr
F8100048	I	0	0	0	0					
F8100050						II	1	1	0	1
F8100052						III	1	1	1	0
F8100078	IV	0	0	0	0					
F8100083	I	0	0	0	0					
F8100093						II	0	0	0	0
Total:		a	b	a	b		a	b	a	b
		0	0	0	0		2	2	1	1
		a+b		a+b			a+b		a+b	
		0		0			4		2	
		CI		CI			CI		CI	
		0		0			6		6	

Intact Score = $\frac{CI}{2 \times \text{No. of Sites on test}}$ $\frac{0}{(2 \times 3)} = 0.00$

Abraded Score = $\frac{CA}{2 \times \text{No. of Sites on test}}$ $\frac{6}{(2 \times 3)} = 1.00$

Total Score = $\frac{CI + CA}{2 \times \text{No. of Sites on test}}$ $\frac{6}{(2 \times 6)} = 0.50$

Primary Skin Irritation Index Category I

Remarks: Non-occluded

APPENDIX B-4

Summary of Primary Skin Irritation Test Data

GLP Study No. 81026 Chemical Name Control Conc N/A Solvent N/A Amt Applied None Code D
 Date of Application 1 Sep 81
 Principal Investigator CPT Jederberg

Irritation Scores

		Intact Skin Sites				Abraded Skin Sites				
Rabbit No.	Site	Erythema		Edema		Site	Erythema		Edema	
		24 hr	72 hr	24 hr	72 hr		24 hr	72 hr	24 hr	72 hr
F8100048						III	1	0	0	0
F8100050	I	0	0	0	0					
F8100052	IV	0	0	0	0					
F8100078						III	0	0	0	0
F8100083						II	0	0	0	0
F8100093	I	0	0	0	0					
Total:		a	b	a	b		a	b	a	b
		0	0	0	0		1	0	0	0
		a+b		a+b			a+b		a+b	
		0		0			1		0	
		C ^I +		C ^A +						
		0					1			

Intact Score = $\frac{C^I}{2 \times \text{No. of Sites on test}}$ $\frac{0}{(2 \times 3)} = 0.00$

Abraded Score = $\frac{C^A}{2 \times \text{No. of Sites on test}}$ $\frac{1}{(2 \times 3)} = 0.17$

Total Score = $\frac{C^I + C^A}{2 \times \text{No. of Sites on test}}$ $\frac{1}{(2 \times 6)} = 0.08$

Primary Skin Irritation Index Category I

Remarks Non-occluded

